K091687

JUL - 7 2009

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. **Submitter's Name:** **IEI Technology Corp.**

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Contact:	Mr. Tom Chen

2. **Device Name :**

Trade Name:	**PACSmate** Model no.: **MMD-4300C/MMD-4300CX**
Common Name:	Image display system, medical image workstation, image monitor/display, and others
Classification name	System, image processing, radiological

3. **DEVICE CLASS** The **PACSmate MMD-4300C/4300CX** has been classified as

   Regulatory Class: II
   Panel: Radiology
   Product Code: LLZ
   Regulation Number: 21CFR 892.2050

4. **Predicate Device:** The predicate device is the **COLOR LCD MONITOR, FLEXSCAN MX300W (K073340)** marketed by **EIZO NANAO CORPORATION.**

5. **Intended Use:** **PACSmate MMD-4300C/4300CX** is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. **PACSmate MMD-4300C/4300CX** does not support the display of mammography images for diagnosis.

6. Device Description: The **PACSmate MMD-4300C/4300CX** is a 30" monochrome/color LCD display for medical image viewing.4 Mega pixel medical grade LCD monitor with high resolutions.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **PACSmate MMD-4300C/4300CX** has the same intended use and similar technological characteristics as the **COLOR LCD MONITOR, FLEXSCAN MX300W (K073340)** marketed by **EIZO NANAO CORPORATION.** Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **PACSmate MMD-4300C/4300CX** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IEI Technology Corp.
% Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corp. (USA)
2904 N. Boldt Drive
FLAGSTAFF AZ 86001

JUL - 7 2009

Re: K091687
Trade/Device Name: PACSmate, Model No.: MMD-4300C/MMD-4300CX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 5, 2009
Received: June 10, 2009

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091687

Device Name: **PACSmate**
Model No.: MMD-4300C/MMD-4300CX
IEI Technology Corp.

Indications For Use:

PACSmate MMD-4300C/4300CX is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. **PACSmate MMD-4300C/4300CX** does not support the display of mammography images for diagnosis.

Prescription Use V (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091687